

**Rational Pharmaceutical Management Plus
Visit to Madagascar to Provide Technical Assistance for the
Development of an Implementation Plan for the Transition to
Artemisinin-Based Combination Therapies for Malaria Treatment:
Trip Report**

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About RPM Plus

The Rational Pharmaceutical Management Plus (RPM Plus) Program, funded by the U.S. Agency for International Development (cooperative agreement HRN-A-00-00-00016-00), works in more than 20 developing countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

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ACRONYMS

ACT	Artemisinin-based combination therapy
BCC	behavior change communication
CHD	Centre hospitalier de district
CMM	Consommation Mensuelle Moyenne des médicaments
CRESAN	Crédit Sanitaire (World Bank-funded NGO)
CSB	Centre de Santé de Base
DAM	Direction Agence des Médicaments
DHS	Demographic and Health Surveys
DPL	Direction des pharmacies et laboratoires
EMAD	Equipe de management du district
EML	Essential Medicines List
GF, GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
HMIS	health management information system
IEC	information, education, and communication
IMCI	Integrated Management of Childhood Illnesses
IPM	Institut Pasteur de Madagascar
MAC	Malaria Action Coalition
M&E	monitoring and evaluation
MOH	Ministry of Health
MSH	Management Sciences for Health
NGO	nongovernmental organization
PhaGCom	Pharmacie à gestion communautaire
PhaGDis	Pharmacie de Gros de District
PSI	Population Services International
RBM	Roll Back Malaria [Partnership]
RDT	rapid diagnostic tests
RPM Plus	Rational Pharmaceutical Management Plus Program
RUMER	Registre d'Utilisation des Médicaments et des Recettes
SALAMA	[Madagascar drug procurement and distribution authority]
SLP	Service de Lutte Paludisme
SSD	Service de Santé du District
STGs	standard treatment guidelines
UNICEF	United Nations Children's Fund
USAID	U.S. Agency for International Development
WHO	World Health Organization

BACKGROUND

Management Sciences for Health's (MSH) Rational Pharmaceutical Management Plus (RPM Plus) Program has received funds from USAID to develop strategies to implement malaria policies and to provide technical assistance in drug management issues for malaria. RPM Plus is a key technical partner in the USAID Malaria Action Coalition (MAC), a partnership among four technical partners: The World Health Organization (WHO), working primarily through its Africa Regional Office (AFRO), the US Centers for Disease Control (CDC), the ACCESS Program of JHPIEGO and RPM Plus.

Malaria is a major cause of morbidity and mortality in Madagascar. As part of its efforts to reduce the public health impact of malaria, Madagascar is currently reviewing its malaria case management policy and plans to adopt an artemisinin-based combination treatment (ACT) to replace chloroquine as the first-line treatment of choice for uncomplicated malaria as recommended by the World Health Organization (WHO). In support of this new policy, RPM Plus as part of the MAC, has received funding from USAID/Madagascar to provide technical assistance to the Madagascar Ministry of Health (MOH) to develop an operational plan for the transition to ACT.

Purpose of Trip

Willy Kabuya-Mutshipayi from RPM Plus traveled to Antananarivo, Madagascar to provide technical assistance to the MOH to develop an operational plan for the change of the first-line treatment for malaria from chloroquine to ACT. The purpose of this trip was to provide guidance to implementers at all levels on the actions that need to be taken when changing the national policy for the first-line treatment for malaria to an ACT and to identify other areas in which technical assistance might be required from RPM Plus and other partners.

Scope of Work

- Provide an arrival briefing and/or departure debriefing to USAID upon request.
- Work with the MOH, SALAMA and other RBM partners to develop an implementation plan for the effective transition to ACT.
- Meet with the MAC local consultant and determine potential future work.

ACTIVITIES

Work with the MOH, SALAMA and other RBM partners to develop an implementation plan for the effective transition to ACT.

1. Meeting with NMCP

Several meetings were held with the SLP staff that plays the role of NMCP in Madagascar. Dr. Tafangy Philemon and his staff provided important information on the evolution of resistance in Madagascar, the decision to change the malaria first-line treatment, the progress with GFATM proposals and the RBM partnership in Madagascar. At present, Madagascar has two grants signed from R3 and R4 with part of it for ACT. CRESAN II is the PR.

However, given the ACT high cost, there were different points of view among partners whether they should be changing to ACT – as recommended by WHO – or another combination treatment. There was a need to advocate the use of ACT to the reluctant partners and to ensure their involvement in planning the implementation of ACT.

In the private sector, ACTs are prescribed and taken without follow-up. There is the potential for problems related to adherence and possible misuses.

Technical assistance from RPM Plus was requested for:

- Finalizing the implementing plan, particularly the phasing-in of ACT, and phasing-out of chloroquine
- Revision of STGs
- Improvement of pharmacovigilance system
- Home-based management with ACT

2. Meeting with SALAMA (Mr Tahina Andrianjafy, Commercial Director)

SALAMA is the drug procurement and distribution authority in Madagascar. SALAMA collaborates with the Direction des Pharmacies, Laboratoires et Medecine Traditionnelle (DPLMT) and the Direction Agence des Médicaments (DAM).

SALAMA was funded in 1996 with support from EU and French cooperation. It operates as a non profit organization and collaborate with MOH based on an MOU reconducted each 10 years. Drugs distributed by SALAMA are all generic and registered in the essential drugs list (EDL). ACT is not yet in the Madagascar EDL and is not included in the distribution through SALAMA. SALAMA procurement is tender-based, both international (80%) and local (20 %). Local production has a lower market due to importation taxes loaded on raw materials.

SALAMA organizes drug distribution from its warehouses in Antananarivo to provinces and districts. It has developed logistic capability to face bad road conditions and thus assure quality for all *Pharmacie de Gros de District (PhaGDis)* orders. When necessary, SALAMA rents helicopters to accelerate pharmaceutical distribution. The delivery delay is a maximum of one month throughout the country, and SALAMA is ready to adapt its distribution system to the shelf life of drugs distributed.

SALAMA is represented in each of the 6 provinces by a team including medical doctor, pharmacist and accountant. The roles of this team are: collection of orders and payments, stock follow-up at all levels, and advice for quality in the service offered. SALAMA assures drug quality control with international and local laboratories.

Between the margins added by SALAM and the health facilities cost, there is an increase of 35%. Of this, 9 % goes to the *PhaGDis*, and the rest goes to the health facility.

3. Meeting with DAM (Dr. Jean René Randriasamimanana)

The Madagascar Drug Agency (DAM) is the drug regulatory authority of Madagascar. It works with a procedures manual developed in 1998. The Agency is in charge of :

- Drug registration
- Quality assurance and quality control
- Licensing of pharmaceutical activities, including manufacturing, import, export, wholesaling and retailing of drugs

There are about 2000 products registered to date. DAM statistics says 75 % of drugs circulation in the country is controlled by the private sector. The EDL is reviewed every two years when not affected by administration changes. The last change occurred in 2004. ACTs are already registered for private importation in Madagascar, but they are not yet on the national EDL. The table below indicates ACTs registered to date.

Brand	Generic	Origin/Manufacturer
ARTEMAX	Dihydroartemisinin	G.A. Pharmaceuticals
ARTESIANE	Artemether	Dafra pharma
ARTESUNATE	Artesunate	FRMAD
ARSUMAX	Artesunate	SANOFI
ARSUCAM	Artesunate + Amodiaquine	SANOFI
ARTEFAN	Artesunate + Lumefantrine	Ajanta pharma
COARTEM	Artemether - Lumefantrine	NOVARTIS

Prices of ACT in the private sector range from 130,000 – 200,000 FMG (15 – 25 USD).

The quality control service of DAM has appropriate equipment, however, due to the lack of reagents, they are only testing chloroquine at present.

Training in pharmacovigilance was identified as a potential area for MAC support. At present the pharmacovigilance system does not function.

4. Field visits

RPM Plus visited two peripheral districts during this mission. The first visit was to Vatomandry SSD, PhaGDis, PhaGCom and health facilities at all levels. Observations made during this visit focused on the overall management of malaria at the facility and community level, and the

organization of drug procurement and distribution in the public sector in Madagascar. The second visit was to Miarinarivo where the mission focused on the sentinel surveillance in highlands.

5. RBM briefing meeting

The mission objectives were presented to all RBM partners to help meet their expectations. Participants at the meeting were the NMCP staff and all partners present in Madagascar: USAID, WHO, PSI, UNICEF, WB, CRESAN, IPM, EU. The main issues that partners raised at this meeting were: evidence of high resistance to chloroquine, high cost of ACT, alternative combined treatment and the phasing in/ phasing out plan. The agenda of RPM mission to visit available partners was reviewed at the end of that meeting. Annex 1 contains the list of people consulted. The mission schedule is listed in Annex 2.

6. RBM debriefing meeting

Upon request of the Ministry of Health, the debriefing meeting was held Tuesday, May 11, 2005. RPM Plus presented findings and recommendations which were discussed by all RBM partners. As a result, the Ministry stated his commitment to the finalization of ACT implementation plan and the procurement of ACT.

Provide an arrival debriefing and/or departure debriefing to USAID upon request (Dr. Noe Rakotondrajaona and Dr. Wendy Benazerga)

A meeting was held with USAID on Monday, May 2, 2005 to discuss technical assistance from RPM Plus to Madagascar for ACT implementation. RPM Plus was briefed on USAID malaria activities of other USAID-funded programs such as PSI, particularly their intervention in malaria home-based management. Dr Noe accompanied RPM Plus to most of the meetings and field visits.

NEXT STEPS

Immediate Follow-up Activities

1. Provide technical assistance to the NMCP to finalize detailed quantification of ACT to be ordered for 21 districts where Madagascar will start implementation.
2. Provide technical assistance to RBM partners to build productive working groups in the steering committee.
3. Complete the ACT implementation plan.
4. Begin planning for follow-up visits to provide continued TA.

(See Table 1)

Table 1: Areas of technical support required to scale up malaria treatment policy change and implementation for the next 36 months

Description of Technical Assistance required	Timeline	Priority	Who will provide required TA?
	Within 6 months = May '05 - Sept. '05 Within one year = By April '06 Within 18 months = By Oct. '06 Within 36 months = By April 2008	1 = Essential for ACT implementation and scale up 2 = Important but not essential 3 = Nice but not critical	If NMCP has already identified a non-MAC agency to provide TA, write the name of the agency; Otherwise write MAC (MAC partner/s)
1. Policy Change and Implementation			
Organize national consensus meeting on policy change and adoption of new drug policy in Madagascar	Within 6 months	1	MAC
Revise STG (to include new treatment policy) and train health workers at all levels including private sector	Within 6 months	1	RPM Plus, WHO
Train microscopists in CHD1s and CSB2s (integrate with microscopist training plan for TB and Leprosy as proposed in GFATM 5th round)	Within 18 months	3	MAC, IPM
Conduct scientific meetings with private health workers on ACT versus monotherapies in malaria case management	Within 6 months	2	MAC
Quantify CQ available in country and describe smooth process of removal from the public sector	Within 18 months	1	RPM Plus, WHO
Quantify ART+AQ need and describe smooth introduction and implementation scaling up	Within 18 months	1	RPM Plus, WHO
Organize training of health workers in the public and private sector on ACT	Within 6 months	1	MAC
Launch GFATM order of ACT from R3 and R4 grant at least 7 months prior the date decided to start ACT use	Within 6 months	1	GFATM / PR NMCP

Strengthen malaria drug efficacy monitoring system (through continuous testing of current and other treatments: ART+AQ; ARTH-LUM; CQ; SP)	Within 36 months	2	MAC, IPM
Strengthen Pharmaco-vigilance system (through development of tools, training of sentinel sites HWs and supervision)	Within 18 months	2	MAC, IPM
2. Financing and Resource Mobilization			
Capitalize GFATM round 3 & 4 grants to launch ACT implementation, and Develop R5 proposal (focused on health systems strengthening including procurement of ACTs) for grant application	Within 6 months	1	MAC
Advocate for additional funding to Madagascar for ACT implementation scaling up	Within 36 months	2	MAC
3. Planning and Coordination			
Set up Steering committee with TORs and technical working groups (Case management, Drug supply, Advocacy & communication, M&E, product quality & pharmacovigilance)	Within 6 months	1	MAC
4. Drug Management			
Strengthen FEFO existing system and recommend PhaGDis to provide information on ACT stocks and expiry dates on a monthly basis	Within 12 months	2	MAC
Develop pharmacovigilance reporting formats, train sentinel sites health workers and supervise the system	Within 12 months	2	MAC
Strengthen and extend quality assurance service capability to ACT and existing tracers drugs (capacity building, equipment and reagents)	Within 12 months	2	MAC
4. Behavior Change Communication			
Reproduce and disseminate revised IEC materials on new malaria treatment drug policy	Within 6 months	1	MAC

ANNEX 1.

PEOPLE CONSULTED DURING MISSION

Name	Organization	Position
Dr. Jean René Randriasamimanana	Agence des médicaments	Director
Tahina Andrianjafy	Salama	Commercial Director
Eliane RazaFimandimby	PSI	ITN Coordinator
Dr. Eric Ratsaravolana	PSI	Palustop Coordinator
Lalah Rambeloson	PSI	Operations Director
Dr. Noe Henri Rakotondrajaona	USAID	Health Population and Nutrition officer
Dr. Wendy Benazerga	USAID	Health Population and Nutrition Team Leader
Dr. Luciano Tuseo	WHO	RBM Medical Officer
Dr André Ndikuyeze	WHO	WR
Jessica Northey	EU	Program Manager
Dr. Khaled Bensaïd	UNICEF	Health and Nutrition Program Officer
Barbara Bentein	UNICEF	Representative
Anwar Bach-Baouab	WB	Lead Operation officer
Jean Pierre Manshande	WB	Senior Health specialist
Dr. Paul Richard Ralainirina	CRESAN II	National Coordinator
Dr. Mosa Milaso	DULMT	Director
Dr. Philemon Tafangy	NMCP	Chef de Service
Dr. Hary Ravony Harintsoa	MAC	Consultant
Tadisoa Veronique Louise	CSB1 AMPITABE	Dispensatrice PhaGCom
Michel Zacharie Rakotoniaino	CSB1 Ampitabe SSD Brickaville	Responsable
Dr. Rajeuson Raymond Marcel	SSD Vatomandry	MID
Dr. Rakotoniary Hery	SSD Vatomandy	Deputy MID
Dr. Paul Marie Serge Rakotoarivony	CSB2 urban Vatomandry	Chief MD
Zaraso Perline	CSB2 urban Vatomandry	Dispensatrice PhaGCom
Fleurette Razafiarisoa	PhaGDis Vatomandry	In-charge of drug distribution
Dr. Antoine Talarmin	IPM	Director

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ANNEX 2.

MISSION ACTIVITY SCHEDULE

Date	Time	Activity	Organizer
Sunday 1 May	1:35 p.m.	Arrival	USAID Mission
Monday 2 May	8:30 a.m.	Meeting with USAID Missison	USAID Mission
	11:00 a.m.	Meeting with the Director of Agence du Médicament:	USAID Mission
Tuesday 3 May	10:00 a.m.	Briefing with RBM partners	NMCP USAID Mission
	14:30 p.m.	Meeting with WHO	USAID Mission
	16:00 p.m.	Meeting with SALAMA	USAID Mission
Wednesday 4 May	8:30 a.m.	Meeting with World Bank	USAID Mission
	10:30 a.m.	Meeting with UNICEF	USAID Mission
	14:30 p.m.	Meeting with PSI technical staff	USAID Mission
Thursday 5 May		Trip to Vatomandry, nalaria endemic areas	USAID Mission
Friday 6 May		Sites visit in Vatomandry (SSD, PhaGDis, CSB2, CSB1)	USAID Mission
Saturday 7 May	10:00 a.m.	Discussion with local MAC consultant and NMCP	NMCP
Monday 9 May	9 a.m.	Meeting with WR WHO	NMCP
	4:00 p.m.	Meeting with Antoine Talarmin, Institut Pasteur	USAID Mission
Tuesday 10 May		Visit to Miarinarivo Sentinel Site	USAID Mission
		Debriefing with the Minister of Health and RBM partners	NMCP
Wednesday 11 May	10 a.m.	Meeting with R 5 proposal elaboration team	NMCP
Thursday 12 May	5 a.m.	Returning	USAID Mission